

REMARKS

Status of Claims and Amendment

Claims 18-35 are all the claims pending in the application. Claim 29 has been amended to delete “which”. No new matter is added.

Supplemental Comments for Response to Rejection Under 35 U.S.C. § 112, Second Paragraph

Further to Applicants’ response in the Amendment filed February 27, 2009, the following additional comments are respectfully requested to be considered by the Examiner with regard to claims 27 and 28. Applicants note that the informative probes selected for the individual known to have breast cancer of claim 27 and for the individual suspected to have breast cancer of claim 28 is based upon hybridization of these probes to those informative probes selected for very early stage breast cancer of claim 18. Applicants note that the intention is that one would select probes that were informative for the breast cancer under study from those which had been selected as being informative for very early breast stage cancer.

Reconsideration and withdrawal of the rejection under § 112, second paragraph, is respectfully requested.

Response To Advisory Action Mailed March 20, 2009

Initially, Applicants thank the Examiner for withdrawal of the written description rejection of claims 27-29, in light of Applicants’ reply.

The Advisory Action indicates that the Amendment under 37 C.F.R. § 1.116 filed February 27, 2009, was not entered because the amendments to the claims raise new issues that would require further search and/or consideration by the Examiner.

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No. 10/727,576 (Q65721)

Specifically, the Examiner asserts that the amendment to claim 29 would raise a new objection because the claim recites “isolating 10 or more mRNA or cDNA species which according to the method of claim 18.” The Examiner suggests amending claim 29 to delete “which”, so that the amendment may be entered and would overcome the § 112, second rejection of record.

In this regard, Applicants note that claim 29 has been amended as suggested by the Examiner. Thus, any grounds of objection to claim 29 should be mooted. Further, withdrawal of the § 112, second rejection with regard to claim 29, as indicated by the Examiner, is respectfully requested.

The Examiner also asserts that Applicants’ arguments that the method of Ralph is concerned with a comparison of gene expression levels from patients with metastatic cancer is not persuasive. The Examiner appears to assert that Ralph must be considered for all it teaches, namely, Ralph expressly teaches that their invention is intended to include organ defined cancers. The Examiner also notes the additional arguments regarding a Declaration made by Applicants, but states that since a Declaration was not filed the arguments are not considered. Also, the Examiner asserts that even if the Declaration was filed with the Amendment, the Declaration would not have been entered because it would not have been considered to be timely filed since this rejection was first presented in a Non-Final Office Action.

Applicants submit herewith a Rule 132 Declaration by Dr. Mackay as indicated in the Amendment filed February 27, 2009. As discussed in the Rule 132 Declaration and the Amendment of February 27th, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to extend the teachings of Ralph to all organ defined cancers

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U.S. Application No. 10/727,576 (Q65721)

such as very early stage breast cancer and that there would have been no expectation of success in performing such a method for the reasons set forth in the Amendment filed February 27, 2009 and the Rule 132 Declaration. Specifically, the premise of the Declaration is that although Ralph refers to organ defined cancers, in view of what is known about prostate cancer, it would have been understood to apply to only certain types of organ defined cancers, namely those which exhibited metastatic potential or which were already metastatic and thus had either circulating cancer cells in the peripheral blood (metastatic) or debris or cellular components from those cells or from cells with metastatic potential.

Further, because the present Declaration is submitted with a Request for Continued Examination (RCE), entry and consideration of the Declaration is appropriate.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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